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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,812	12/14/2004	Harald Breivik	10260.0006-00000	8613

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EXAMINER	
CARR, DEBORAH D	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
10/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,812	BREIVIK ET AL.	
	Examiner	Art Unit	
	DEBORAH D. CARR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34-35,38,42-43, 45-48, 50 and 59-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,34,35,38,42,43,45-48,50 and 59-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/09,8/09,9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 27 July 2009 have been fully considered but they are not persuasive. The rejection of claims 32, 34-35, 38, 42-43, 45-48, 59-64 under 35 USC§102(b) is maintained.

2. The rejection of claims 32-39, 42-50, 59-61 under 35 USC§112, 1st paragraph has been withdrawn. However they a newly rejected under 35 USC§112, 1st paragraph.

3. Claims 1-31, 33, 36-37, 39-41, 44, 49, 51-58 have been canceled.

4. Claims 32, 34-35, 38, 42-43, 45-48, 50 and 59-64 are pending.

5. The indicated allowability of claims 47-50, 59 is withdrawn.

(New) Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 32, 34-35, 38, 42-43, 45-48, 50 and 59-64 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims:

The claims are directed towards pharmaceutical compositions and it's use in treating at least one cardiovascular disease in particular hypertriglyceridaemia wherein the pharmaceutical composition contains a marine oil comprising eicosapentaenoic acid ethyl ester and docosahexaenoic acid ethyl ester in a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia, wherein the concentration of brominated flame retardants in the pharmaceutical composition is less than 0.2 µg/kg as measured by the concentration of BDE 47, and wherein said pharmaceutical composition is not a health supplement.

Amount of direction provided by the inventor and existence of working examples:

Regarding the pharmaceutical compositions pharmaceutical composition contains marine oil comprising eicosapentaenoic acid ethyl ester and docosahexaenoic

acid ethyl ester in a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia is not present nor are working examples..

***State of the prior art and level of predictability in the art*:**

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability.

The physiological art is recognized as unpredictable. (MPEP 2164.03.) In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention:

The relative skill would be one versed in the treatment of cardiovascular diseases wherein hypertriglyceridaemia is the disease being treated.

Page 15 of the specification refers to a pharmaceutical composition that can be used to treat hypertriglyceridaemia but no disclosure about treatment dosages.

Based on applicants argument that the FDA has established that the known compositions contain these components cannot be use to be administered as a pharmaceutical, experimentation would be needed to ascertain the pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia.

(Old) Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 32, 34-35, 38, 42-43, 45-48, 50, 59-64 rejected under 35 U.S.C. 102(b) as being clearly anticipated by EPAX Product Specifications for EPAX 4020EE or 5500EE or 6000EE or 6010EE.

Applicant argues that the instant invention reads on a pharmaceutical composition not a health supplement. Based on the FDA recommendations the approved amounts are not feasible to be pharmaceutically effective concentration to therapeutically treat hypertriglyceridemia.

Since applicant has not given any direction regarding dosages that would be considered to be pharmaceutically effective concentration to therapeutically treat hypertriglyceridemia, it is unclear how it can be stated the references does not

anticipate the instant invention. It is clear that the compositions taught in the art cited supra can be administered in such a way to therapeutically treat hypertriglyceridemia.

Pharmaceutical use is defined as any use, other than as food, wherein a substance is used on or in the body to prevent, diagnose, alleviate, treat, or cure a disease in humans or animals. While applicants have labeled the EPAX compositions as health supplements one would not describe them as food or food supplements but as compositions with pharmaceutical use.

Applicant's on page 14 starting at line 20 that the composition can be a health supplement or pharmaceutical thereby making these two terms or utilities interchangeable. Again since there is no direction in the specification regarding the dosage then one would appear that the dosage is the same when given as a health supplement or pharmaceutical.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc